ALLEGED SHIPMENT: Between the approximate dates of December 8, 1944, and March 6, 1945, from the State of New York into the States of Pennsylvania, Connecticut, and Oklahoma.

LABEL, IN PART: "A Pro-Medico Product 3,500 cc Estrogenic Substance in Oil Each cc contains Estrogenic Substance derived from equine urine," "Estrogenic Hormones Multiple Dose Vial A sterile solution in ampul oil of estrogenic substances derived from equine urine * * * Manufactured for The Vale Chemical Co., Inc. Allentown, Penna.," "Gynestrin Estrogenic Hormones An oil solution of estrogenic hormones, derived from equine urine," and "Obenoids – Pink Each Tablet Contains—Phenobarbital ¼ grain."

NATURE OF CHARGE: *Estrogenic substance.* Adulteration, Section 501 (d), estrogenic substance other than as it naturally occurs in and is extracted from equine urine and containing little or no estrone, had been substituted for estrogenic substance as it naturally occurs in and is extracted from equine urine, which the product purported and was represented to be. Misbranding, Section 502 (a), the label statement "Estrogenic Substance derived from equine urine" was false and misleading.

Gynestrin estrogenic hormones. Adulteration, Section 501 (d), estrogenic hormones other than as they naturally occur in and are extracted from equine urine, had been substituted for estrogenic hormones as they naturally occur in and are extracted from equine urine, which the product purported and was represented to be. Misbranding, Section 502 (a), the label statement "Estrogenic Hormones derived from equine urine" was false and misleading.

Obenoids. Misbranding, Section 502 (a), the label statement "Contains—Phenobarbital" was false and misleading since the product contained no phenobarbital; and, Section 502 (e) (2), the product was not sold under a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the name and quantity and proportion of atropine that it contained.

DISPOSITION: On March 1, 1949, a motion by the defendant for a bill of particulars was granted to the extent of requiring the Government to state how many International Estrone Units per cubic centimeter were contained in the estrogenic substance in oil referred to in counts 1 and 3 of the indictment. On December 12, 1949, pleas of nolo contendere were entered and the corporation was fined $900, and the individual defendant was fined $9 and placed on probation for 6 months.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2963. Misbranding of Nue-Ovo. U. S. v. 24 Units * * * (and 12 other seizure actions). Cases consolidated and tried to the court. Government's motion for summary judgment granted. Decree of condemnation and destruction. (F. D. C. Nos. 24649, 24709, 24728, 24840, 24850, 24859, 24874, 24891, 24894, 24895, 24908, 24909, 25101. Sample Nos. 14542-K, 27743-K, 28167-K, 28524-K, 28564-K, 28983-K, 29337-K, 31354-K, 36794-K, 37343-K, 37615-K, 40523-K, 40622-K, 40624-K.)

*See also Nos. 2951, 2961, 2962.

LIBELS FILED: Between April 21 and July 16, 1948, Eastern and Western Districts of Washington, District of Kansas, Northern District of Illinois, District of Colorado, Southern District of California, Eastern and Western Districts of Missouri, and District of Utah.

ALLEGED SHIPMENT: Between the approximate dates of December 31, 1947, and June 10, 1948, by Research Laboratories, Inc., from Portland, Oreg.

PRODUCT: Nue-Ovo. 117 units, each containing 3 bottles; 24 cases, each containing 6 cartons of 3 bottles each; 7 cases, each containing 18 bottles; and 9 cartons and 57 bottles, at Seattle and Pasco, Wash.; La Crosse, Kans.; Chicago, Ill.; Denver, Colo.; Vernon, Calif.; St. Louis and Kansas City, Mo.; and Salt Lake City, Utah.

LABEL, IN PART: (Bottle) "Nue-Ovo * * * Active Ingredients: An aqueous extraction of Plume Thistle, Burdock, Quassia, Sage, Cinnamon, Horehound, Ginseng, Calamus, Dandelion, Althea, Kola Nut, Sodium Salicylate, Cascara, Licorice, Vitamin B_1."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in leaflets entitled "Information on Nue-Ovo" accompanying one shipment of the article and the statement "Nue-Ovo for Rheumatism and Arthritis" appearing on the shipping case labels of the other shipments of the article were false and misleading. The statements represented and suggested that the article was effective in the treatment of rheumatism and arthritis, whereas the article was not effective in the treatment of those conditions.

DISPOSITION: The libel proceedings having been consolidated for purposes of trial in the Northern District of Illinois, and Research Laboratories, Inc., having appeared as claimant, the matter came on for hearing before the court on the Government's motion for a summary judgment. On October 11, 1949, after considering the arguments of counsel and briefs filed in support of and against the motion, the court handed down the following decision:

CAMPBELL, *District Judge:*

"This is a consolidation of six cases, all involving the same subject matter. The proceedings are brought pursuant to libels alleging misbranding, under 21 U. S. C. A. 352 (a), of a certain product known as Nue-Ovo, which is manufactured by the claimant, Research Laboratories, Inc. In all cases but one the shipping case label bears the statement 'Nue-Ovo for Rheumatism and Arthritis.' In the remaining case, circulars entitled 'Information on Nue-Ovo,' which were shipped with the article, bear the statement 'Nue-Ovo * * * to be used in the treatment of Arthritis and Rheumatism.' It is the contention of the Government that the statement in each case is false and misleading, in that its ultimate effect is to represent and suggest that the article is effective in the treatment of arthritis and rheumatism, whereas the article is not so effective.

"Libellant now moves for summary judgment on the basis of estoppel by judgment, i. e., that judgments have previously been rendered in favor of the libellant in the United States District Court of the Western District of Washington in the case of United States of America vs. 143 Packages, more or less, each containing 3 bottles of 'Nue-Ovo' (1943), and in the case of United States of America vs. 600 units, more or less, each containing 3 bottles of 'Nue-Ovo' (1946). The latter judgment was affirmed in 167 F. 2nd 410; certiorari denied 335 U. S. 843. Claimant opposes the motion on the ground that different issues of law and fact exist in the present cases.

"Although the claimant admits the wording set forth on the shipping cases and circulars, it cites the language of the back bottle label in support of its contention:

IMPORTANT

Many users believe NUE-OVO has brought them relief, but experts differ as to its merits. It is prescribed by some doctors although not generally accepted by the medical profession. If it does not relieve you after a fair trial in accordance with the directions, discontinue its use. Any guarantee to induce the purchase of NUE-OVO is unauthorized.

"It is claimant's position, therefore, that the present consolidated actions present the issues of whether (1) the labeling represents that there is a difference of medical opinion as to the effectiveness of the product in the treatment of arthritis and rheumatism, and (2) there is in fact such a difference of medical opinion, whereas in the previous actions it had only to be determined whether the product was represented to be effective in the treatment of those diseases and whether it was so effective.

"Claimant's argument is untenable. In effect, the supposedly new issues were presented to and disposed of by the Court of Appeals of the Ninth Circuit in Research Laboratories vs. United States, 167 F. 2nd 410:

> Summarized, the appellant's attacks upon the judgment below are as follows:
>
> 1. The court below erred in submitting issues to the jury, since every statement in the labeling as to the effectiveness of the product is a statement of opinion, and at the conclusion of the case the record showed nothing more than a difference of opinion among qualified experts as to the effectiveness of the product.

However, the Court of Appeals concluded that the evidence adduced at the trial went beyond a mere expression of difference in medical opinion, and that the jury could and did properly decide that the opinions presented by the claimant's witnesses were to be rejected. The rule has been most lucidly stated in U. S. vs. 7 Jugs, etc., of Dr. Salsbury's Rakos:

> . . . If the evidence is such that it appears that the question of effectiveness has not transcended the realm of demonstrable fact, the court must hold as a matter of law that assertions of effectiveness are not false and refuse to submit the question to the jury. American School of Magnetic Healing vs. McAnnulty, supra; see L. B. Silver Co. vs. Federal Trade Commission, 6 Cir., 1923, 289 F. 985; cf. Bruce vs. United States, 8 Cir., 1912, 202 F. 98. But where the evidence indicates that there is a standard of demonstrable truth and fact by which the jury can measure the claims of effectiveness, the court should then submit the question to the jury under appropriate instructions. What the evidence shows in a given case is a question of law for the court to decide. * * * * *
> . . . Certainly, where factual proof is present which indicates the worthlessness of the remedies in question, mere injection of an alleged difference of opinion on the part of persons whom the jury might find were either ignorant or charlatans, could not operate to prevent the jury from deciding the question of effectiveness. Under the evidence in this case, the jury was entirely warranted in finding that the contrary expressions of opinion by the witnesses appearing for claimant were in direct opposition to established scientific fact.

"Since, therefore, the juries in the previous cases determined that the product was ineffective in the treatment of arthritis and rheumatism, they must necessarily have rejected as valueless the testimony of the witnesses appearing on behalf of the claimant. In other words, a finding that there was not an honest difference of opinion as to effectiveness, was an essential ingredient of the conclusion that the product was ineffective. Furthermore, the quality of the testimony would not be altered here, in view of claimant's offer to stipulate that the same medical and lay witnesses as were produced by claimant and libellant in the case of U. S. vs. 600 Units, etc., supra, would testify to the same extent in the instant case.

"It still remains, however, to be decided whether all issues presented in this litigation are res judicata. The doctrine was ably defined in Henderson vs. United States Radiator Corp., 78 F. 2nd 674:

> The doctrine of res judicata embodies two main rules which may be stated as follows:
>
> (1) The final judgment or decree of a court of competent jurisdiction upon the merits concludes the parties and their privies to the litigation, and constitutes a bar to a new action or suit upon the same cause of action either before the same or any other tribunal.
>
> (2) Any right, fact or matter in issue and directly adjudicated, or necessarily involved in the determination of an action before a competent court in which a judgment or decree has been rendered upon the merits, is conclusively settled by the judgment therein and cannot again be litigated between the same parties and their privies, whether the claim, demand, purpose or subject-matter of the two suits is the same or not.
>
> The principle of the first rule is referred to as "bar by former judgment," and the second as "conclusiveness of judgment."

Each of the articles involved in these consolidated cases bears an identical label. This label lists the ingredients as follows: 'An aqueous extraction of Plume Thistle, Burdock, Quassia, Sage, Cinnamon, Horehound, Ginseng, Calamus, Dandelion, Althea, Kola Nut, Sodium Salicylate, Cascara, Licorice, Vitamin B_1.' These ingredients are identical with the ingredients of the article which was involved in three and part of the fourth of the cases consolidated in U. S. vs. 600 Units, etc. These ingredients are also essentially the same as the ingredients of the article involved in the other part of the fourth case in the

above case and in U. S. vs. 143 Packages, etc. This element, combined with the determinations, both direct and necessarily implied, of the juries in the previous cases as to effectiveness, clearly brings the instant action within the doctrine of res judicata as enunciated in the Henderson case, supra.

"The entire history of the manufacture and sale of Nue-Ovo is marked by questionable promotional methods. This most recent mode of labeling is merely another subtle maneuver adopted for the purpose of avoiding the dictates of the Food and Drugs Act and inducing a gullible public to purchase a worthless product for the cure of rheumatism and arthritis. The language of U. S. vs. 95 Barrels of Vinegar, 265 U. S. 438, equally well describes the activities of the claimant in the instant action:

> The statute is plain and direct. Its comprehensive terms condemn every statement and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.

"Accordingly, therefore, the Government's motion for summary judgment is granted. The Government is hereby directed to submit to the Court, within 15 days, a form of judgment and a form of decree of forfeiture and condemnation."

On November 16, 1949, in accordance with the above decision, a decree was entered providing for condemnation and destruction of the product.

2964. Misbranding of Remin's Brewers' Hydrolyzed Yeast Powder, Remin's Multi-Vitamin A-B-C-D Drops, Remin's Brewers' Hydrolyzed Yeast and Whey Powder, and Remin's (Powdered) Hydrolyzed Brewers' Yeast Vegetables and Whey. U. S. v. Eugene A. Kazmark (M & M Service). Plea of guilty. Fine, $10. (F. D. C. No. 25624. Sample Nos. 16849–K to 16852–K, incl.)

INFORMATION FILED: August 4, 1949, Northern District of Illinois, against Eugene A. Kazmark, trading as M & M Service, at Joliet, Ill.

ALLEGED SHIPMENT: On or about April 13, 1948, from the State of Illinois into the State of Wisconsin.

LABEL, IN PART: "Remin's Brewers' Hydrolyzed Yeast (Powder) A Supplementary source of Hydrolyzed Brewers' Yeast and its natural vitamins B_1 and B_2," "Remin's Multi-Vitamin A-B-C-D Drops In A Base Of Brewers' Yeast Extract," "Remin's Brewers' Hydrolyzed Yeast and Whey Powder A Supplementary source of Hydrolyzed Brewers' Yeast and its natural vitamins B_1 and B_2," and "Remin's (Powdered) Hydrolyzed Brewers' Yeast Vegetables and Whey."

NATURE OF CHARGE: *Remin's Brewers' Hydrolyzed Yeast Powder, Remin's Brewers' Hydrolyzed Yeast and Whey Powder*, and *Remin's (Powdered) Hydrolyzed Brewers' Yeast Vegetables and Whey.* Misbranding, Section 502 (a), certain statements in booklets and in a leaflet accompanying the articles were false and misleading since the articles would not be efficacious for the purposes, and would not fulfill the promises, of benefit stated and implied. The booklets were entitled "Remin's * * * Descriptive Price List," "Facts About Vitamins, Amino Acids and Hydrolysates," "Keep in Step with the March of Progress," and "For Protein Vitality Try Remin's Hydrolyzed Yeast," and the leaflet was entitled "Miracle Cure Laid to Diet." The false and misleading statements in the booklets and in the leaflet represented and suggested that the articles would be efficacious in the cure, mitigation, treatment, and prevention of fatigue, sleeplessness, nervousness, neuritis, poor appetite, loss of strength, constipation, and skin disorders; that the articles would be efficacious in the prevention of poliomyelitis (infantile paralysis),